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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 13

Application Number: 09/945,731
Filing Date: November 10, 1997
Appellant(s): Cros et. al.

William P. Berridge, Esq.
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed May 5, 2000.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed on May 5, 2000 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims of Group I (3, 17 and 22), Group II (1, 2, 11-16 and 18-21), Group III (5 and 23), Group IV (6), Group V (7), Group VI (8), Group VII (9), and Group VIII (10) do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

A substantially correct copy of appealed claim 3 appears on page A-2 of the Appendix to the appellant's brief. The minor errors are as follows: At line 13 of Claim 3, a typographical error occurs where it recites "10-2 M". This should state **10^{-2} M** (emphasis added).

(9) Prior Art of Record

5,912,032 HOFFMAN ET. AL. 3-27-1990

5,508,164 KAUSCH ET. AL. 4-16-1996

5,122,600 KAWAGUCHI ET. AL. 6-16-1992

EP 161,881 MITSUI TOATSU CHEMICALS 11-21-1985 ("Itoh")

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3 and 5-23 are rejected under 35 U.S.C. 103(a). This rejection is set forth in prior Office action, Paper No. 10.

(11) Response to Argument

1. The Appelants' Brief, Paper No. 12 asserts in section "A." that the rejection of claims 1-22 under 35 USC 103(a) did not properly consider the prior art as set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966) by improperly determining the scope and content of the prior art and the level of the ordinary skilled artisan.

The obviousness rejection (above) is entirely within the guidelines as set forth in Graham v. John Deere Co. The quotes from the text of the references demonstrate this fact.

2. Paper No. 12 asserts at page 5, item "B. 1." that Itoh (EP 161,881) does not teach appropriate conditions at which nucleic acids are attached to the polymer.

Itoh is used in combination with Hoffman (4,912,032), Kawaguchi (5,122,600) and Kausch (5,508,164) to demonstrate that the appropriate conditions for attaching the nucleic acids to the polymer were well known to those of skill in the art at the time of filing of the instant application. (see especially Hoffman at columns 4-5).

3. Paper No. 12 asserts at Page 5, item "B. 1. a." that Itoh taught away from binding nucleic acids at low temperatures and releasing nucleic acids at higher temperatures because the sections in Itoh which describe the use of binding molecules at low temperatures and releasing molecules at higher temperatures make no specific mention of nucleic acids.

Itoh clearly teaches the binding molecules at low temperatures and releasing molecules at higher temperatures , as admitted by the above statement. Since there is no specific mention of nucleic acids in the quoted passages, the rejection must therefore be an obviousness type rejection, and not an anticipatory rejection, but it is clear from the text that Itoh taught the binding of molecules at low temperatures and releasing molecules at higher temperatures. The teachings of Itoh are clear that molecules can be bound at low temperatures and released at high temperatures, and in combination with the teachings of Hoffman (see especially Hoffman at column 4, line 45 bridging to column 5, line 28) one of skill in the art would immediately know that one could use the gels for binding nucleic acids at low temperatures and releasing nucleic acids at higher temperatures, especially since Hoffman used the gels in a manner

consistent with the instant invention as described in examples 3 and 4 at pages 17-20 of the instant specification.

4. Paper No. 12 asserts in section "B. 1. b." that Itoh does not teach or suggest cross-linked polymers containing cationic monomers.

At page 50, lines 4-11, Itoh stated "more selective holding and release become feasible by the use of a copolymer with an ionic monomer as the copolymer, because the use of such an ionic monomer permits introduction of either one of the ionic properties, namely either cationic property or anionic property into the resultant copolymer and the ionic interaction can also be used upon holding various substances".

5. Paper No. 12 asserts in section "B. 1. c." that Itoh does not teach or suggest a pH at most equal to 7 or an ionic strength at most equal to 10^{-2}.

Itoh taught at page 48, line 25 bridging to page 49, line 9 "[i]t is also possible to carry out the holding and release by controlling the pH of an aqueous solution. Namely, is in the case of an ampholyte electrolyte such as amino acid or protein, its holding can be effected preferentially at pHs below the isoelectric point of the ampholyte electrolyte on the acidic side. On the alkaline side, its release can be effected preferentially at pHs above the isoelectric point of the ampholyte electrolyte. In other words, the holding and release can be controlled by temperature and pH." While this section does not discuss nucleic acids, one of skill in the art would recognize the well known use of pH, with respect to the isoelectric point of a molecule

to bind and release a charged molecule such as a nucleic acid, similar to the teachings of Itoh as they were applied to an amino acid or protein.

6. Paper No. 12 asserts in section "B. 1. d." that Itoh does not provide any motivation to use the invention to isolate nucleic acid material.

Itoh taught the use of the method to isolate nucleic acid material at page 44, line 13 bridging to page 45, line 13, where it clearly states that nucleic acids are among the "valuable materials" intended for use in their teachings.

7. Paper No. 12 asserts in section "B. 2" that Hoffman does not teach or suggest the subject matter of Group I. Group I being drawn to a process of isolation of nucleic acids with a lower critical solubility temperature (LCST) polymer gel by adsorbing the nucleic acid onto the LCST polymer gel in a solution with an ionic strength buffer of at most equal to 10^{-2} , a pH at most equal to 7, and a temperature less than the LCST of the polymer.

This is not a true statement, since Hoffman taught some of the limitations of the claimed subject matter (see the rejection above). The obviousness rejection is presented to show the elements of the invention which were made obvious by Hoffman, and Hoffman is not relied upon in the rejection above to demonstrate all of the limitations of the claimed subject matter, in which case Hoffman would anticipate the claimed subject matter.

Paper No. 12 goes on to argue that the Hoffman did not teach the adsorption of DNA or RNA to the gel.

At column 5, lines 11-21 Hoffman states "[d]epending upon the substance of interest, the binding pair may be an affinity pair, or, alternatively, the binding pair may be a less specific binding pair....ion with chelator, ionophore complexer; and stable-free radical with free radicals". This teaching of Hoffman makes it clear that the nucleic acid may be bound by ionic forces to the polymer, or "adsorbed" to the polymer.

8. Paper No. 12 asserts in section "B. 3" that it is not proper to combine Itoh and Hoffman to produce the instant invention because Hoffman did not teach the holding of substances to the polymer by the swell and shrink of the gel.

Hoffman taught at column 4 line 45 to column 5, line 10 the binding and release of molecules by the shrink and swell of the gel.

9. Paper No. 12 asserts in section "B. 4" that Kawaguchi does not teach the ionic strengths at which DNA is bound to or released from the polymer.

Since the only limitation in the claims which pertains to this line of argument is drawn to a low ionic strength (ie. 10^{-2}) buffer, the other limitations discussed in this argument are not claimed, and as such are not relevant to the issues of the rejection, except to state that the nucleic acid binds to the gel in a low ionic strength buffer, which is taught in general terms in Itoh, and in Hoffman at figure 6 (see the rejection above).

10. Paper No. 12 asserts in section "B. 5." that Kausch does not teach or suggest high salt concentrations for the release of biological materials from the magnetic bead support.

Kausch taught at column 9, lines 11-16 that high salt may be used to release biological materials from the solid support material.

11. Paper No. 12 asserts in section "C." that Hoffman did not teach the holding of DNA or RNA by the binding pair on the polymer would be affected by the ionic strength of the buffer.

Hoffman at column 9, lines 27-35 states "[t]he ligand bound substance may then be released from the immobilizing binding pair component by further cycling the gel in an eluting solution that breaks either the bond to the polymer gel or the binding pair bond....The eluting solution may effect the breaking of the bonds or linkage by a change in pH, the presence of certain ions or ionic concentrations...". (The remaining objections have already been addressed above)

12. Paper No. 12 asserts in section "D" that none of the references taught that the particulate support consisted of a functionalized particulate polymer.

(It should be noted that Paper No. 12 misstates the teachings of Hoffman at page 14, lines 13-14 by stating "[a]s a result, the particulate support does not consist of the functionalized, particulate polymer of claim 5". The rest of the argument is then based upon this premise, which premise is therefore incorrect.)

Hoffman taught at column 4, lines 57-60 (see also line 57 bridging to column 5, line 21) that the nucleic acid molecules may bind directly to the polymer, since nucleic acid molecules were in fact the "first binding pair" referred to in this passage, which nucleic acid molecules (the "first binding pair") were bound to functionalized polymer.

13. Paper No. 12 asserts in section "E." that none of the references teach or suggest a particulate support.

Itoh at page 12, described the uses for the polymer in particulate form, and its use to coat a solid support.

Hoffman at column 11, lines 50-59 taught the use of particle supports with a organic or inorganic core, which were coated with the polymer. The core did not affect the adsorption properties of the polymer.

Kausch taught at column 4, lines 14-37, the use of a particulate support which comprises a polystyrene core.

14. Paper No. 12 asserts in section "F." that none of the references taught that the use of a particulate support which comprises a polystyrene core.

Kausch taught at column 4, lines 14-37, the use of a particulate support which comprises a polystyrene core.

15. Paper No. 12 asserts in section "G." that none of the references taught that the use of a magnetic compound which comprises a magnetic core.

Kausch taught at column 4, lines 14-37, the use of a particulate support which comprises an iron-containing (magnetic) polystyrene core.

16. Paper No. 12 asserts in section "H." that none of the references taught that there was at least one probe or primer capable of specifically hybridizing to nucleic acid material, which is added to the sample before or after contacting the absorption reagent and the sample.

Kausch taught in the abstract and in the figures, at least one probe or primer capable of specifically hybridizing to nucleic acid material, which is added to the sample before or after contacting the absorption reagent and the sample. (see below)

17. Paper No. 12 asserts in section "H." that none of the references taught that there was no teaching in the references of a primer was used in order to obtain a hybridization reagent where the hybridization reagent was then hybridized with at least one nucleic acid fragment under conditions for the hybridization or extension of the primer.

Kausch taught at the abstract, and the Figures a probe brought into a hybridization reaction under conditions suitable for hybridization. It should be noted here that the instant specification, at page 8, lines 26-29, defines a primer as a "probe possessing a hybridization specificity under determined conditions for the initiation of an enzymatic polymerization". While the probe of Kausch is not used in an enzymatic polymerization, the probe of Kausch satisfies the definition, since a probe may be used in a hybridization reaction, and under "determined conditions" serve as a primer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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